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10/520,685 05/27/2005 Allan Otto Fog Lihme 030307-0250 9774 22428 7590 10/04/2007 FOLEY AND LARDNER LLP SUITE 500 3000 K STREET NW WASHINGTON, DC 20007 Allan Otto Fog Lihme 030307-0250 9774 EXAMINER HINES, JANA A ART UNIT PAPER NUMBER					
22428 7590 10/04/2007 FOLEY AND LARDNER LLP SUITE 500 3000 K STREET NW WASHINGTON, DC 20007 Mail Date Delivery Model	APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
FOLEY AND LARDNER LLP SUITE 500 3000 K STREET NW WASHINGTON, DC 20007 MAIL DATE BEADWINER HINES, JANA A ART UNIT PAPER NUMBER 1645 MAIL DATE DELIVERY MOD	10/520,685	05/27/2005	Allan Otto Fog Lihme	030307-0250	9774
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)			
· mate	10/520,685	LIHME ET AL.			
Office Action Summary	Examiner	. Art Unit			
	Ja-Na Hines	1645			
The MAILING DATE of this communicatio	n appears on the cover sheet w	ith the correspondence address			
Period for Reply	EDIVIO OET TO EVDIDE 4 M	IONTHIO) OR THIRTY (20) RAVO			
A SHORTENED STATUTORY PERIOD FOR R WHICHEVER IS LONGER, FROM THE MAILIN - Extensions of time may be available under the provisions of 37 C after SIX (6) MONTHS from the mailing date of this communicatic - If NO period for reply is specified above, the maximum statutory p - Failure to reply within the set or extended period for reply will, by Any reply received by the Office later than three months after the earned patent term adjustment. See 37 CFR 1.704(b).	IG DATE OF THIS COMMUNI FR 1.136(a). In no event, however, may a pon. period will apply and will expire SIX (6) MON statute, cause the application to become Al	CATION. reply be timely filed NTHS from the mailing date of this communication. BANDONED (35 U.S.C. § 133).			
Status					
1) Responsive to communication(s) filed on	10 January 2005.				
2a) ☐ This action is FINAL . 2b) ☐					
·— · · ·	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is				
closed in accordance with the practice un	der <i>Ex parte Quayle</i> , 1935 C.D	D. 11, 453 O.G. 213.			
Disposition of Claims	•				
4)⊠ Claim(s) <u>1-26</u> is/are pending in the applic	ation.				
4a) Of the above claim(s) is/are withdrawn from consideration.					
5) Claim(s) is/are allowed.					
6) Claim(s) is/are rejected.					
7) Claim(s) is/are objected to.	•				
8)⊠ Claim(s) <u>1-26</u> are subject to restriction an	d/or election requirement.				
Application Papers					
9)☐ The specification is objected to by the Exa	miner.				
10) The drawing(s) filed on is/are: a)	accepted or b) objected to	by the Examiner.			
Applicant may not request that any objection t	o the drawing(s) be held in abeyar	nce. See 37 CFR 1.85(a).			
Replacement drawing sheet(s) including the c	orrection is required if the drawing	g(s) is objected to. See 37 CFR 1.121(d).			
11)☐ The oath or declaration is objected to by the	ne Examiner. Note the attached	d Office Action or form PTO-152.			
Priority under 35 U.S.C. § 119					
12) ☐ Acknowledgment is made of a claim for fo	reign priority under 35 U.S.C. &	§ 119(a)-(d) or (f).			
a) ☐ All b) ☐ Some * c) ☐ None of:					
1. Certified copies of the priority documents have been received.					
2. Certified copies of the priority documents have been received in Application No					
Copies of the certified copies of the	priority documents have been	received in this National Stage			
application from the International B		*			
* See the attached detailed Office action for	a list of the certified copies not	received.			
	•				
		. •			
Attachment(s)		•			
1) Notice of References Cited (PTO-892)		Summary (PTO-413)			
 2) Notice of Draftsperson's Patent Drawing Review (PTO-94 3) Information Disclosure Statement(s) (PTO/SB/08) 		(s)/Mail Date Informal Patent Application			
Paper No(s)/Mail Date	6) Other:	<u>_</u> .			

Application/Control Number: 10/520,685

Art Unit: 1645

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- I. Claims 1, 3-12 and 19 are drawn to an extracorporeal adsorption method for removing harmful substances responsible of inducing sepsis caused by Gram-negative in a mammal, said extracorporeal adsorption method being effected by an adsorption column assembly, said adsorption column assembly comprising a column and an adsorption medium in the form of particles, the sedimented volume of said particles being at the most 80% of the volume of the column, said particles being characterized by carrying an affinity specific molecule with a specific affinity for the LPS portion of said Gram-negative bacteria, said method comprising treating blood obtained from said mammal by passing the blood through the adsorption column assembly at such a flow rate that a fluidized bed of the particles is formed.
- II. Claims 2 and 14 are drawn to an extracorporeal adsorption method for removing harmful substances responsible of inducing sepsis caused by Gram-negative or Grampositive bacteria in a mammal, said extracorporeal adsorption method being effected by an adsorption column assembly, said adsorption column assembly comprising a column and an adsorption medium in the form of particles, the sedimented volume of said particles being at the most 80% of the volume of the column, said particles being characterized by carrying an affinity specific molecule with a specific affinity for: i) the LPS portion of said Gram-negative bacteria, and/or ii) Gram-positive bacteria or harmful substances derived from said Gram-positive bacteria and the use of an adsorption medium for the preparation of a therapeutic adsorption column assembly for the therapeutic treatment of sepsis caused by Gram-negative or Gram-positive bacteria in a mammal by extracorporeal adsorption, said adsorption column assembly comprising (a) a vessel for continuous obtaining blood from said mammal, (b) a column and the adsorption medium, the sedimented volume of said adsorption medium being at the most 80% of the volume of the column, said adsorption medium being characterized by carrying an affinity specific molecule with a specific affinity for: i) the LPS portion of said Gram-negative bacteria, and/or ii) Gram-positive bacteria or harmful substances derived

from said Gram-positive bacteria, said column is treating the obtained blood by passing the blood through the adsorption column assembly at such a flow rate that a fluidized bed of the adsorption medium is formed, and (c) another vessel which continuously delivers blood back to the patient..

- III. Claims 13, 15, 17-18 and 20-26 are drawn to the use of an adsorption medium for the preparation of a therapeutic adsorption column assembly for the continuous therapeutic treatment of sepsis caused by Gram-negative bacteria in a mammal by extracorporeal adsorption, said adsorption column assembly comprising (i) a vessel for continuous obtaining blood from said mammal, (ii) a column comprising the adsorption medium, the sedimented volume of said adsorption medium being at the most 80% of the volume of the column, said adsorption medium being characterized by carrying an affinity specific molecule with a specific affinity for the LPS portion of said Gramnegative bacteria, said column is treating the obtained blood by passing the blood through the adsorption column assembly at such a flow rate that a fluidized bed of the adsorption medium is formed, and (iii) another vessel which continuously delivers blood back to the patient.
- 2. The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The adsorption medium recited in group III can be used with methods other than those recited in groups I or II. For instance, the adsorption medium can be used in a method to treat sepsis or for the removal of small water-soluble substances. Therefore, the adsorption medium's special technical feature is comprised within the medium and not within the methods steps; therefore the groups lack the same or corresponding technical feature.

Groups I and III, is drawn to an unrelated inventions because it use, function and effect are patentably distinct in comparison to the other groups. Group I has a different special technical feature when compared to the claims of Group III; because the recited components the adsorption column assembly are the special technical features.

Theses special technical features are comprised within their structural differences of the

Application/Control Number: 10/520,685 Page 4

Art Unit: 1645

assembly. Accordingly, the groups lack a corresponding technical feature. Finally, groups I and II are unrelated and do not share a special technical feature because each

method has a separate and distinct purpose with separate and distinct final outcomes

and different particles characterized by their carrying affinity with specific affinity for the

LPS portion of said Gram-negative bacteria, and/or ii) Gram-positive bacteria or harmful

substances derived from said Gram-positive bacteria. Therefore, there is no

corresponding special technical feature between the groups I and II and III.

3. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

- 4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).
- 5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

Application/Control Number: 10/520,685

Art Unit: 1645

supervisor Jeffery Siew, can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines

September 29, 2007

MARK NAVARRO
PRIMARY EXAMINER

Page 5